(2) REMARKS

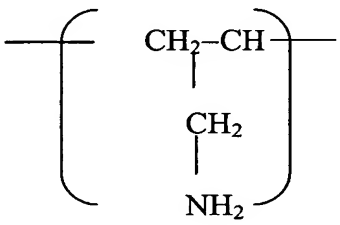
1. Rejection under 35 USC §112, second paragraph.

Claims 1-4 have been rejected under 35 §112, second paragraph because the main claim fails to identify "n" in the formula.

Applicants point out, however, that the term "n" was deleted by amendment filed October 14, 2004. The amendment shows the "n" term to be stricken out, but perhaps the resolution in the office files did not permit this to be easily seen.

It is important to understand that the claims were amended to limit the polyamine (I) (i.e., polyallylamine and polyvinylamine) to only polyallylamine when filing the RCE.

The presently claimed invention is directed to a liquid preparation for contact lenses containing 0.3 to 50 ppm of a polyamine having recurring units of the formula (I):



(I)

namely polyallylamine.

Accordingly, this rejection does not appear founded on the claims as now pending and should be withdrawn.

2. Rejection under 35 USC §103(a).

Claims 1-4 have been rejected under 35 USC §103(a) as being unpatentable over The Patent Abstract of Japan 10319358 (Menicon Co., Ltd.) and The Patent Abstract of Japan 10108899 (Tomey Technol. Corp.) for the reason set forth on pages 2 and 3 of the Office Action of September 24, 2003. This rejection is respectfully traversed because the references do not establish a *prima facie* case of obviousness and the evidence of record is sufficient to overcome mere *prima facie* obviousness.

In reply to the anticipation rejection by JP-A-10-319358 in the first Office Action of January 15, 2003, applicants alleged that the claimed invention is not anticipated by JP-A-10-319358 since the concentrations are different, and that since the purpose for and amount of polyallylamine are materially different, the reference does not provide necessary motivation required under 35 USC 103(a) for a person skilled in the art to use polyallylamine in a lower level than that taught by the reference. Applicants further alleged that since the cited reference does not teach or suggest that polyallylamine has an antibacterial activity, the high antibacterial activity of the claimed composition is unexpected from the cited reference.

In the second Office Action of September 24, 2003, the Examiner took the position that applicants alleged criticality to the differences in concentrations used by the claimed invention in comparison to the ones used by the prior art, but the determination of optimum properties or amounts is within the skill of the art in the absence of evidence to the contrary. The Examiner alleged that applicants had presented no evidence to establish the unexpected or unobvious nature of the claimed invention.

Applicants, however, respectfully disagree with the Examiner. The cited reference does not provide any motivation or suggestion for a person skilled in the art to arrive at applicants' claimed invention. Even if a person skilled in the art would be motivated to use polyallylamine in a low concentration, the antibacterial activity of the claimed composition is unexpected from the cited reference since the reference does not

teach or suggest that the polyallylamine has an antibacterial activity. The data in the specification was further submitted in the form of a Rule 132 Declaration in order to demonstrate that the claimed composition has an unexpected high antibacterial activity. It is believed that the data establish the unexpected or unobvious nature of the claimed invention.

Applicants again call the Examiner's attention to their arguments as set forth in the Response of June 7, 2004 filed in reply to the final Office Action dated April 6, 2004. While these will not be repeated in their entirety here, it is very important to note several points before adding some additional ones based on the current wording of the claims.

To establish *prima facie* obviousness, three basic criteria must be met. According to MPEP §2142, they are: (1) there must be some suggestion or motivation (2) there must be a reasonable expectation of success, and (3) the prior art must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants note that the first criteria is not met because there are no specific reasons are given in the references themselves or from any presentation of logic as to why someone skilled in the art would be motivated to make the modifications necessary to meet the terms of the claims. There is no reasoning given by the examiner on how the person skilled in the art might be motivated from the deficient teachings of the reference to modify those teachings for applicants' new purpose and new concentrations. There is no logical reason apparent from either the reference or the Office Action as to why the person skilled in the art would put aside the teachings of the reference and adapt those teachings to achieve a purpose not taught other than by applicants' own description.

The Office Action also fails to meet the second criteria. There must be a reasonable expectation of success. The rejection set out by the Office Action calls for

changing the teachings of the reference to use less a polyallylamine having allylamine recurring units than its disclosed minimum. There is no reasoning given in the Office Action as to why such a low level would be reasonably expected to work for the disclosed purpose.

Applicants claim use of the claimed composition at concentrations of 0.3 to 50 ppm. This level of use is not disclosed in the prior art, nor is the reason for its use. JP-A-10-319358 teaches using a polyallylamine having allylamine recurring units as a component for suppressing a change of the basic curve of a contact lens at the time of the distribution in a concentration of not less than 0.01 w/v % (*i.e.*, not less than 100 ppm), preferably not less than 0.1 w/v. These prior art levels are not within the range claimed by applicants. Applicants' maximum level is less than half of what the reference suggests as useful for any purpose. The purpose disclosed by JP-A-10-319358 is very different than applicants' purpose, and there is no sound reason of record why one skilled in the art would attempt to use applicants' levels. That applicants have done so and established an effective low concentration for a different utility, is invention – not optimization. Looking at it another way, it is not obvious to optimize an unknown.

From this discussion, it is also apparent that the prior art does not teach or suggest all the claim limitations. It does not teach applicants' concentrations and it does not teach the effect attributed to the low concentration by applicants.

In addition to these points, applicants note that there are several reasons why there is no sufficient reason presented in the prior art of record to shift the burden of proof to applicants.

(1) JP-A-10-319358 clearly teaches that the concentration of polyallylamine is at least 0.01 w/v% (at least 100 ppm), preferably at least 0.1 w/v% (at least 1,000 ppm), and is at most 10 w/v% (100,000 ppm), preferably at most 3 w/v% (30,000 ppm). In Examples 5 and 6 of the reference, polyallylamine is used, the concentrations of which are 1 w/v% (10,000 ppm) and 0.5 w/v% (5,000 ppm).

In the outstanding Office Action, the rejection has been made for the reason set forth on pages 2 and 3 of the Office Action of September 24, 2003. In the Office Action of September 24, 2003, the Examiner takes the view that the feature of concentration is merely determination of optimum concentration within the skill of the art in the absence of evidence to the contrary. However, from the above-mentioned teachings of the reference, it is apparent that at least the optimum concentration of polyallylamine taught by the reference is more than 1,000 ppm. The cited reference does not provide any motivation for a person skilled in the art to use polyallylamine in a concentration of 100 ppm or less.

Furthermore, JP-A-10-319358 is directed to a distributing solution (shipping solution) used for preserving contact lenses in the distribution process until patients purchase the lenses after the manufacturing, which contains (I) polyallylamine and/or (II) a polymer such as a half amide of a maleic anhydride copolymer as a component for suppressing a change of the base curve of a contact lens at the time of the distribution. The reference does not teach or suggest that the polyallylamine has an antibacterial activity.

The reference does not provide any motivation or suggestion which leads a person skilled in the art to use polyallylamine at a lower level than the concentrations taught by the reference. Even if one were to assume motivation for the sake of argument, it is not expected that a solution containing polyallylamine in a concentration of 0.3 to 50 ppm exhibits a high antibacterial activity. The data in the specification and Declaration demonstrate that the claimed composition has a high antibacterial activity as compared with a conventionally used antibacterial agent "polyhexamethylene biguanide (PHMB)". The use of polyallylamine in a concentration of 0.3 to 50 ppm as an antibacterial agent is not optimization of the properties and amounts taught by the reference, since the claimed amount and the antibacterial activity are neither taught nor suggested by the reference. Again, a person skilled in the art cannot optimize what is unknown.

(2) In the outstanding Office Action, the Examiner states that the presented data in the declaration demonstrating the superior activity of the claimed lower concentrations are not clear. The Examiner further states that such data show the log reduction of >3.04 for the comparative examples 1 and 2 for Pseudomonas aeruginosa and 4.16 and 3.86 for Candida albicans, but the log reduction for the claimed composition is >3.57 for Pseudomonas aeruginosa and the log reduction of >3.87 and 1.18 for Candida albicans and, therefore, the above data do not demonstrate the superior antibacterial activity of the claimed composition for Candida albicans.

However, it is believed sufficient for establishing unobviousness to show at least one unexpected result. The reference does not teach or suggest that the polyallylamine has an antibacterial activity. Further, it is believed sufficient that the claimed composition has an antibacterial activity for at least one microorganism. Therefore, even if the antibacterial activity of Example 2 (concentration 1.2 ppm) for Candida albicans is regarded as being low, the composition of Example 2 has a high antibacterial activity for Pseudomonas aeruginosa and, therefore, it is believed that the data in the declaration demonstrate the unexpected or unobvious nature of the claimed invention.

Further, since the cited reference does not teach or suggest that polyallylamine has an antibacterial activity, it is not required to compare the antibacterial activity of the claimed composition with the composition taught by the reference. The Examiner compares the antibacterial activity of Examples 1 and 2 with Comparative Examples 1 and 2 the polyallylamine concentrations (1,200 ppm and 120 ppm) of which fall within the range taught by the reference. However, such comparison is not proper. The claimed composition should be compared with conventional antibacterial agents such as polyhexamethylene biguanide (PHMB). The antibacterial activity (log reduction 1.18 for Candida albicans) of Example 2 (1.2 ppm) is much higher than the antibacterial activity (log reduction 0.46 for Candida albicans) of Comparative Example 4 which contains 1 ppm of a conventional antibacterial agent PHMB.

Furthermore, the antibacterial activity (log reduction 1.18 for Candida albicans) of Example 2 (1.2 ppm) satisfies the ISO standard. A copy of ISO 14729 is enclosed. The disinfecting test made in the specification and declaration corresponds to the stand-alone test described in ISO 14729. According to the ISO, it is required that the log reduction is not less than 3.0 for bacteria (e.g., Pseudomonas aeruginosa), and the log reduction is not less than 1.0 for moulds (e.g., Candida albicans). The conventional antibacterial agent PHMB does not satisfy the requirement of ISO when the concentration is 1 ppm, since the log reduction for Candida albicans is 0.46 (see Comparative Example 4). In contrast, polyallylamine satisfies the requirement of ISO even if the concentration is low, e.g., 1.2 ppm as shown in Example 2, since the log reduction is not less than 1.0. Therefore, it is believed that the data in the declaration also demonstrate the superior antibacterial activity of the claimed composition for Candida albicans.

(3) In the outstanding Office Action at page 3, lines 1-2, the Examiner states that the superior antibacterial activity for Pseudomonas aeruginosa is not well established by the presented examples. We do not well understand the reason why the superior activity is not well established by the presented examples. If the reason is that the antibacterial activity for Pseudomonas aeruginosa of Examples 1 and 2 (log reduction >3.57) is on the same level as or is only slightly higher than that of Comparative Examples 1 and 2 (log reduction >3.04), that is to say, if the Examiner compares the claimed composition with the composition taught by the cited reference, it is believed that such comparison is improper since the reference does not teach or suggest that the composition disclosed therein has an antibacterial activity. If the Examiner still understands that the scope of the claimed polyamines with the $-(CH_2)_n-$ group would encompass many compounds, the Examiner is not correct since the claimed polyamine is now only polyallylamine. The claimed composition satisfies the requirement of ISO for Pseudomonas aeruginosa.

In light of the above, it is believed that the data in the specification or declaration demonstrates the unexpected or unobvious nature of the claimed invention.

(4) JP-A-10-108899 is directed to a liquid preparation for contact lenses containing 0.1 to 10 ppm of polyhexamethylene biguanide (PHMB) as an antibacterial agent to which a non-ionic isotonic agent is incorporated so that PHMB can exhibit the antimicrobial activity at a low concentration.

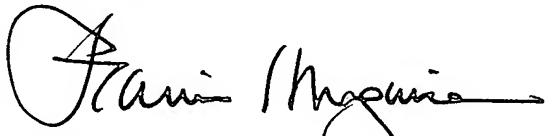
JP-A-10-108899 does not disclose any polyamines.

In the first Office Action dated January 15, 2003, JP-A-10-108899 was cited by the Examiner to show that the use of secondary components such as surface active agent as claimed in claims 2 and 4 in contact lens solutions is old and is well known.

JP-A-10-108899 provides nothing for the deficiency of JP-A-10-319358.

Applicants have made a significant advance in the art and have described it in a manner that clearly distinguishes it patentably from the prior art. In addition, applicants have submitted evidence of unexpected results which is sufficient in nature and weight to overcome a rejection based on *prima facie* obviousness. Accordingly, reconsideration and withdrawal of the rejection and allowance of all pending claims are believed in order, and such actions are earnestly solicited.

Respectfully submitted,



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